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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,247	01/15/2004	Raymond A. Dwek	2543-1-023CON	5331

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/758,247

Applicant(s)

DWEK ET AL.

Examiner

Daniel M. Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-38, as originally filed, are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15, drawn to a method for treating a glycolipid storage-related disorder comprising administering a therapeutically effective amount of an inhibitor of glycolipid synthesis in combination with an agent capable of increasing the rate of glycolipid degradation, classified in class 514.
- II. Claims 16-24, drawn to a method for treating a glycolipid storage-related disorder comprising administering a therapeutically effective amount of an inhibitor of glycolipid synthesis in combination with bone marrow transplantation, classified in class 424, subclass 93.1.
- III. Claims 25-38, drawn to a pharmaceutical composition comprising an inhibitor of glycolipid synthesis and an agent capable of increasing the rate of glycolipid degradation, classified in class 514.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to distinct methods. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together in a single method and have different modes of operation and function, as the method of Group I is limited

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to administration of an agent capable of increasing the rate of glycolipid degradation while the method of Group II is limited to comprising bone marrow transplantation.

In the absence of an allowable product claim to which the process claims are limited to making or using, examining the methods of Groups I and II together in a single application would impose a serious burden on the Office. *Prima facie* evidence for the additional burden imposed by examining each additional method is evidenced by the separate classification of each method. Furthermore, as each method is limited to comprising elements to which the other methods are not limited, examination of each method requires a separate search for those elements that distinguish the respective methods. In addition, because each method encompasses subject matter not encompassed by the other method, a determination that any one method is patentable over the art does not adequately support patentability of the other method. Therefore, patentability of each method must be determined separately.

Invention III is related to the methods of Groups I and II as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed reads on any composition comprising an inhibitor of glycolipid synthesis and an agent capable of increasing the rate of glycolipid degradation, which could be used *in vitro* or in tissue culture to study processes of glycolipid synthesis and degradation. Thus, the product can be used in processes that are materially different from the processes of Groups I and II.

Although the Office acknowledges that in the event a product claim is deemed allowable, determining patentability of process claims that depend from or otherwise include all the limitations of the allowable product claim does not impose an undue burden (*Infra.*), no such determination of patentability has been made in the instant case. In the event that the product is not patentable, a determination of whether each method of making and using the product is patentable over the art is based upon the particulars of the method and not on the product made by or used in the method. Conversely, a search of any given process of making or using the product does not adequately support patentability of the product because the product can be made by or used in a materially different process. Therefore, until the product is deemed allowable, search and examination of the process claims with the product imposes an undue burden on the Office. As discussed in detail below, if a product claim is found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

Rejoinder in view of *In re Ochiai*, *In re Brouwer*

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Requirement for Election of Species

This application contains claims directed to the following patentably distinct species of the claimed invention: Each of the processes of Groups I or II and the product of Group III, wherein the inhibitor of glycolipid synthesis is selected from the species set forth in claims 2-8

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(Group I), claims 17-24 (Group II) or claims 26-33, wherein the agent capable of increasing the rate of glycolipid degradation is selected from the species set forth in claims 10-13 (Group I) or claims 34-37 (Group III), and wherein the glycolipid storage related disorder is selected from the species set forth in claim 14 (Group I), claim 25 (Group II) or claim 38 (Group III).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant should elect a single species of inhibitor of glycolipid synthesis, a single species of agent capable of increasing the rate of glycolipid degradation and a single species of the glycolipid storage related disorder for examination with the elected Group. It is noted that some claims are directed to subgenera of species set forth in the claims (*e.g.*, the subgenus of glucosylceramide synthesis inhibitors that are imido sugars). Where subgeneric claims are present, Applicant should elect a single species within the subgenus for examination.

Currently, claims 1 and 2 are generic to the species set forth in claims 3 and 4; claim 1 is generic to the species set forth in claim 5; claims 1 and 6 are generic to the species set forth in claims 7 and 8; claims 1 and 10 are generic to the species set forth in claim 11; claim 1 is generic to the species of claims 12-14; claims 16 and 17 are generic to the species of claims 18 and 19; claim 16 is generic to the species of claim 20; claims 16 and 21 are generic to the species of claims 22 and 23; claims 25 and 26 are generic to the species of claims 27 and 28; claim 25 is generic to the species of claim 29; claims 25 and 30 are generic to the species of claims 31 and 32; claims 25 and 34 are generic to the species of claim 35; and claim 25 is generic to the species of claims 36-38.

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

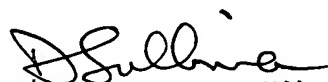
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M Sullivan, Ph.D.
Examiner
Art Unit 1636

12/21/05


DANIEL M. SULLIVAN
PATENT EXAMINER